CLAIMS

WE CLAIM:

1. A method for treating a condition responsive to paliperidone comprising orally administering a capsule shaped tablet core dosage form containing paliperidone wherein the dosage form releases the paliperidone at a substantially ascending release rate for a prolonged period of time.

2. A method for administering an active agent to a subject comprising:

Administering a dosage from to the subject wherein the dosage form comprises:

(a) a capsule shaped tablet core comprising a plurality of layers wherein a drug composition contains an active agent in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane surrounding the capsule shaped tablet core to form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the semipermeable membrane into the compartment; and

(c) an orifice formed through the semipermeable membrane and into the capsule shaped tablet core to permit the active agent to be released from within the compartment into the external fluid environment;

wherein the dosage form releases the active agent at a substantially ascending release rate for a prolonged period of time.

3. A method for administering an active agent to a subject comprising:

Administering a dosage from to the subject wherein the dosage form comprises:

(a) a capsule shaped tablet core comprising a plurality of layers wherein a composition containing about 50-60% of an active agent, about 5-15% of a structural polymer carrier and about 15-40% of a solubilizing

surfactant is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane surrounding the capsule shaped tablet core to form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the semipermeable membrane into the compartment; and

(c) an orifice formed through the semipermeable membrane and into the capsule shaped tablet core to permit the active agent to be released from within the compartment into the external fluid environment;

wherein the dosage form releases the active agent at a substantially ascending release rate for a prolonged period of time.

4. The method according to Claim 2 wherein the active agent is paliperidone.

5. The method according to Claim 2 wherein the active agent is risperidone.

6. The method according to Claim 2 wherein at least a first drug composition layer comprises an osmagent and a second drug composition layer does not comprise an osmagent.

7. The method according to Claim 6 wherein the osmagent is sodium chloride salt.

8. The method according to Claim 7 wherein the osmagent is at least 20% of the first layer drug composition.

9. The method according to Claim 6 wherein the first drug composition layer is proximal to the exit orifice.

10. The method according to Claim 4, wherein the capsule shaped tablet core comprises two layers and the paliperidone is contained within a first

layer and the fluid-expandable polymer is contained within a second layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

11. The method according to Claim 4, wherein the capsule shaped tablet core comprises three layers and a portion of the paliperidone is contained within a first drug composition layer and the remaining portion of the paliperidone is contained within a second drug composition layer, wherein the portion of paliperidone contained within the first layer is less than the portion of paliperidone contained within the second layer, and wherein the fluid-expandable polymer is contained within a third layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

12. The method according to Claim 11 characterized by producing a substantially ascending blood plasma concentration of paliperidone.

13. The method according to Claim 12 wherein a C_{max} occurs after about 14 hours after administration to the subject.

14. The method according to Claim 12 wherein a C_{max} occurs between about 16 hours and about 22 hours after administration to the subject.

15. The method according to Claim 12 wherein a C_{max} occurs between about 18 hours and about 21 hours after administration to the subject.

16. The method according to Claim 10, wherein the proportion of paliperidone contained within the first layer to the paliperidone contained within the second layer is less than 1.0.

17. The method according to Claim 10, wherein the proportion of paliperidone contained within the first layer to the paliperidone contained within the second layer is less than about .33.

18. The method according to Claim 10 wherein the concentration of paliperidone in the first drug layer to the concentration of paliperidone in the second drug layer is less than .44.

19. The method according to Claim 10 wherein the concentration of paliperidone in the first drug layer to the concentration of paliperidone in the second drug layer is less than .33.

20. The method according to Claim 11, wherein the first layer comprises an osmagent and the second layer comprises no osmagent.

21. The method of Claim 20 wherein the osmagent is at least 20% of the first layer.

22. A method for delivering an active agent, the method comprising orally administering to a subject a capsule shaped tablet dosage form containing an active agent wherein the dosage form releases the active agent from the dosage form at a substantially ascending release rate for a prolonged period of time.

23. The method of Claim 22 wherein the active agent is paliperidone.

24. The method according to Claim 23, wherein the dosage form comprises:

(a) a capsule shaped tablet core containing a plurality of layers wherein paliperidone is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane surrounding the capsule shaped tablet core to form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the semipermeable membrane into the compartment; and

(c) an orifice formed through the semipermeable membrane and into the capsule shaped tablet core to permit paliperidone to be released from the compartment into the external fluid environment.

25. The method according to Claim 24, wherein the capsule shaped tablet core comprises two layers and the paliperidone is contained within a first layer and the fluid-expandable polymer is contained within a second layer and the orifice is formed through the semipermeable membrane adjacent to the first layer.

26. The method according to Claim 24, wherein the capsule shaped tablet core comprises three layers and a portion of the paliperidone is contained within a first layer and the remaining portion of the paliperidone is contained within a second layer, wherein the portion of paliperidone contained within the first layer is less than the portion of paliperidone contained within the second layer, and wherein the fluid-expandable polymer is contained within a third layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

27. The method according to Claim 26, wherein the proportion of paliperidone contained within the first layer to the paliperidone contained within the second layer is less than 1.0.

28. The method according to Claim 26, wherein the proportion of paliperidone contained within the first layer to the paliperidone contained within the second layer is less than about .33.

29. The method according to Claim 26 wherein the concentration of paliperidone in the first drug layer to the concentration of paliperidone in the second drug layer is less than .44.

30. The method according to Claim 26 wherein the concentration of paliperidone in the first drug layer to the concentration of paliperidone in the second drug layer is less than .33.

31. The method according to Claim 26, wherein the first layer comprises an osmagent and the second layer comprises no osmagent.

32. The method of Claim 31 wherein the osmagent is at least 20% of the first layer.

33. A capsule shaped tablet dosage form comprising a drug layer composition having an active agent wherein the dosage form, following oral administration to a subject, releases the active agent from the dosage form at a substantially ascending release rate for a prolonged period of time.

34. The dosage form of Claim 33 wherein the active agent is paliperidone.

35. The dosage form according to Claim 34 comprising:

(a) a capsule shaped tablet core containing a plurality of layers wherein the paliperidone is contained in at least one layer and at least one other layer comprises a suitable fluid-expandable polymer;

(b) a semipermeable membrane surrounding the capsule shaped tablet core to form a compartment having an osmotic gradient to drive fluid from an external fluid environment contacting the semipermeable membrane into the compartment; and

(c) an orifice formed through the semipermeable membrane and into the capsule shaped tablet core to permit paliperidone to be released from within the compartment into the external fluid environment.

36. The dosage form according to Claim 35, wherein the capsule shaped tablet core comprises two layers and the paliperidone is contained within a first layer and the fluid-expandable polymer is contained within a

second layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

37. The dosage form according to Claim 35, wherein the capsule shaped tablet core comprises three layers and a portion of the paliperidone is contained within a first layer and the remaining portion of the paliperidone is contained within a second layer, wherein the portion of paliperidone contained within first layer is less than the portion of paliperidone contained within the second layer, and wherein the fluid-expandable polymer is contained within a third layer and the orifice is formed through the semipermeable membrane adjacent the first layer.

38. The dosage form according to Claim 37, wherein the proportion of paliperidone contained within the first layer to the paliperidone contained within the second layer is less than 1.0.

39. The dosage form according to Claim 37, wherein the proportion of paliperidone contained within the first layer to the paliperidone contained within the second layer is less than about .33.

40. The dosage form according to Claim 37 wherein the concentration of paliperidone in the first drug layer to the concentration of paliperidone in the second drug layer is less than .44.

41. The dosage form according to Claim 37 wherein the concentration of paliperidone in the first layer to the concentration of paliperidone in the second drug layer is less than .33.

42. The dosage form according to Claim 37, wherein the first layer comprises an osmagent and the second layer comprises no osmagent.

43. The dosage form of Claim 37 wherein the osmagent is at least 20% of the first layer.

44. The dosage form of Claim 37 characterized by releasing the paliperidone from the dosage form at a substantially ascending rate of release for about 10 hours to about 14 hours.

45. The dosage form of Claim 37 characterized by releasing the paliperidone from the dosage form at a substantially ascending rate of release for about 14 hours to about 18 hours.

46. The dosage form of Claim 37 characterized by releasing the paliperidone from the dosage form at a substantially ascending rate of release for about 18 hours to about 20 hours.

47. The dosage form of Claim 37 characterized by having a T_{90} from the core occurring at about 20 hours.

48. The dosage form according to Claim 35 further comprising a subcoat for reducing the rate of degradation of paliperidone, which subcoat comprises a hydroxyalkylcellulose polymer possessing a 8,500 to 4,000,000 molecular weight that at least partially surrounds the core and is positioned between an inside surface of the semipermeable membrane and the core.

49. The dosage form according to Claim 35 further comprising a subcoat for reducing the rate of degradation of paliperidone which subcoat comprises a mixture of hydroxypropyl cellulose and providone prepared in ethanol that at least partially surrounds the core and is positioned between an inside surface of the semipermeable membrane and the core.